

AMENDMENT AND RESPONSE TO RESTRICTION
AND ELECTION OF SPECIES REQUIREMENTS
Application No.: 10/588,205

Atty. Docket No.: Q96421

REMARKS

This Amendment, filed in reply to the Office Action dated August 19, 2010, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable consideration on the merits is respectfully requested.

Claims 1-11 are all the claims pending in the Application and are currently amended herewith solely to improve clarity and conciseness.

Specifically, independent claim 1 is amended to require an "artificial" membrane.

Support for this amendment can be found throughout the specification as filed including on page 3, lines 22-27, which states:

"The membrane preferably contains as the amphiphilic molecule an amphiphilic copolymer having a hydrophilic and a hydrophobic portion. It is particularly preferred for the membrane of the vesicle according to the invention to be formed from amphiphilic block copolymer molecules, and it is very particularly preferred for the membrane to be formed from a single type of amphiphilic block copolymer molecules." (emphasis added)

Applicants contend that a person of ordinary skill in the art reading the teachings of the specification would understand that the membrane of the vesicle is necessarily artificial and that the vesicles are prepared, for example, as described in Example 2 of the specification.

Entry and consideration of this amendment are respectfully requested.

Response to Restriction Requirement and Election of species

The Examiner requests restriction of the claims to one of the following Groups:

Group I Claim 2, drawn to a vesicle comprising a pore-forming unit and a binding substance that cannot substantially traverse the pore, wherein the binding

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substance contains a chemical structure to form either an ionic, hydrogen, or hydrophobic bond.

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| Group II | Claim 3, drawn to a vesicle comprising a pore-forming unit and a binding substance that cannot substantially traverse the pore, wherein the pore contains a protein selected from a Markush group of structures. |
| Group III | Claim 4, drawn to a vesicle comprising a pore-forming unit and a binding substance that cannot substantially traverse the pore, wherein the inside pore diameter is 1nm or less. |
| Group IV | Claim 5, drawn to a vesicle comprising a pore-forming unit and a binding substance that cannot substantially traverse the pore, wherein the formed pore is enantio-selective. |
| Group V | Claims 6-7, drawn to a vesicle comprising a pore-forming unit and a binding substance that cannot substantially traverse the pore, wherein the interior of the vesicle contains a positively charged polymer (it is noted that an oligomer is a polymer). |
| Group VI | Claims 8-11, drawn to methods of binding and releasing a substance and a nucleic acid, respectively, to the vesicle of Claim 1. |

The Examiner also requires that Applicant select one of the following species for prosecution on the merits.

If Applicant should elect Invention I, a bond type from Claim 2

If Applicant should elect Invention II, an alpha-helix or beta barrel

The Examiner contends the special technical feature is a vesicle comprising amphiphatic molecules and a pore-forming unit in a membrane. The Examiner then asserts a prokaryotic or eukaryotic cell reads on claims 1-7. Hence, the restriction is allegedly proper.

Restriction Requirement

The Applicants elect Group V, claims 6-7 for examination on the merits. This election is made with traverse.

With respect to restriction practice for National Stage Applications, the requirements for Unity of Invention are promulgated in PCT Rules 13.1 and 13.2 that state:

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13.1 Requirement: The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").
(Emphasis added)

13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled: Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. (Emphasis added)

Hence for Unity of Invention to exist, PCT Rule 13.2 requires that the:

- (1) groups share a technical feature and
- (2) the technical feature makes a contribution over the prior art²

Conversely, lack of unity may be evident if:

- (1) *a priori*, before consideration of prior art, the groups do not share a same or corresponding technical feature or
- (2) *a posteriori*, after a search of the prior art, the shared technical feature fails to make a contribution over the prior art³

Applicants have amended claims 1-11 to require an "artificial" membrane. In view of currently amended claim 1 and the specification as filed, the membranes of the claimed invention are evidently distinct from prokaryotic and eukaryotic cells. Applicants therefore assert the special technical feature is a vesicle having an artificial membrane and containing a binding substance. Unity of Invention under PCT Rule 13.2 therefore does exist because claims 1-10 are all directed to a vesicle with an artificial membrane and claim 11 requires a method of releasing

² Contribution over the prior art is considered with respect to novelty and inventive step (PCT International Search and Preliminary Examination Guidelines (ISPE) Paragraph 10.02)

³ PCT International Search and Preliminary Examination Guidelines (ISPE) Paragraph 10.03

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a nucleic acid using a vesicle with an artificial membrane. Moreover, the Applicants affirm this special technical feature makes a contribution over the prior art.

Hence, contrary to the Examiner's assertion, Applicants assert there is Unity of Invention under PCT Rule 13.2 and respectfully request that the Restriction Requirement be withdrawn.

Election of Species Requirement

In response to the Examiner's requirement, Applicant elects an alpha-helix for examination on the merits. Claim 3 encompasses the elected species.

Applicant submits that if any of the elected claims is found to be allowable, claims dependent there from should similarly be considered allowable in the same application. Applicant reserves the right to file a Divisional Application directed to non-elected claims 1-5 and 8-11.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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